## **EC Declaration of Conformity**

Manufacturer:

Authorized EU Representative:

Name: Changzhou Sifary Medical Technology Co., Ltd. Address: No. 99, Qingyang Road, Xuejia County, Xinbei District, Changzhou City, Jiangsu Province, China 213000

Name: Landlink GmbH Address: Dorfstrasse 2/4, 79312. Emmendingen, Germany

We, the manufacturer, herewith declare that the products **Apex Locators** UMDNS-Code: 16355

meet the provisions of Directive 93/42/EEC as amended by Directive 2007/47/EC which apply to them.

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

**(** € 0197

The product concerned has been designed and manufactured under a quality management system according to Annex ∨ of Directive 93/42/EEC as amended by Directive 2007/47/EC. and in conformity with the national standards transposing harmonised standards. Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

> **TÜV Rheinland LGA Products GmbH** Tillystraße 2, 90431, Nürnberg, Deutschland, Germany

Certificate No.: DD 60134397 0001 Issue date: 28.12.2018 Expiry date: 13.06.2022

following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC as amended by Directive 2007/47/EEC.

Application of the above mentioned Annexes and the intervention by the Notified Body is limited to: manufacture concerned with the conformity of the products with the metrological requirements. The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Changzhou Sifary Medical Technology Co., Ltd. Address: No. 99, Qingyang Road, Xuejia County, Xinbei District, Changzhou City, Jiangsu Province, 213000, China

General Manager

Legally binding signature, Function